"EXHIBIT"

P-8188.00
LB 010
MRA

Invention Disclosure

1. Inventors

Michael Thomas Lee [illegible]
Nancy Perry Pool T3(

2. Title of invention

Large-scale Processing Loop for Implantable Medical Devices

3. How others have addressed this problem:

- Use of people to analyze data and implement changes in device therapy
- Limiting features and functions of implantable medical devices to those that can be processed by the device itself.

4. The invention is described here for

5. ---

6. Discuss problems that the device is designed to solve, referring to any prior devices of a similar nature:

Human physiological systems are very complex and nonlinear. Implantable medical devices attempt to interact with these physiological systems, but often can only work with simplified models or the most elemental of the systems. These limitations are chiefly driven by two issues: an incomplete understanding of the characteristics of the physiological system, and a lack of raw computing power on the part of the implantable device.

Computing power (processor capability, memory, adequate power supply) is abundantly available in the non-implantable ('external') world. The computing industry is still following Moore's Law (stating that transistor density will double every 18 months), delivering increasingly sophisticated computing devices yearly.

Models of physiological systems researched and developed on powerful external computing systems are often valuable in the medical world, but are not suitable for use in implantable medical devices. Cases involving long-term monitoring or forecasting are particularly well-suited to external computing systems.

Implantable medical devices are in a unique position to monitor physiological systems continuously. High resolution data can be collected, but implantable devices are ill-suited to storage and processing of large amounts of complex physiological data. External systems can deal with the complexity and amount of data, but are not suitable for implantation.

This invention proposes to link the power of the external computing world to the implantable medical device via a network of communications devices.

Problems that can be solved:

- long-term disease progression (e.g. heart failure, hypertension, diabetes) can be monitored, and therapies adjusted appropriately, with reduced need for human intervention
- complex nonlinear control systems can be used with implantable device therapy
- the amount of historical data used as input to control systems can be virtually unlimited
- more thorough comparison can be made between patients with similar diseases as data and therapy direction are centralized
- data from other medical systems (implanted or external) can be incorporated easily into the control system

7. State the advantages of the invention over presently known devices, systems or processes.

- this invention allows implantable medical devices access to virtually unlimited computing power as part of their data collection and therapy calculation processes
- implantable medical devices would not need to continually ramp up the amount of processing power they contain
- control system algorithms could be more easily updated due to the centralized nature of this invention (rather than individually updating thousands of implanted medical devices)
- patients can benefit from other patient's experiences faster and more accurately
- a virtually unlimited amount of patient historical data can be used as input to therapy control systems
- data and therapy from multiple devices can be orchestrated

8. List all known and other possible uses for the invention:

- high resolution data collection and storage from implantable medical devices
- use of complex control systems to manage therapy of implantable medical devices
- use of large amounts of physiological data as input to therapy algorithms
- use of data from multiple implantable and external medical devices as input to therapy and diagnostic algorithms
- ability to orchestrate the data collection and therapy functions of implantable medical devices
- ability to use high-power computing systems directly in implantable medical device therapy
- ability to centralize therapy prescription
- ability to compare disease states, diagnostic data and therapy prescription across patients in great detail

- ability to update control system software and hardware at a central location to benefit all patients

9. Specifically describe the invention and its operation.

The invention is composed of the following systems:

- implanted medical device(s) such as a pacemaker, defibrillator, drug pump, neurological stimulator, physiological signal recorder; singly or in combination;
- external devices that communicate with the implanted medical device via radiofrequency, and also communicate with a data network via modem, LAN, WAN, wireless or infrared means;
- a data network that allows the external communications device access to the computing center from many locations;
- and a computing center with the ability to collect and process large amounts of physiological data using complex control systems.

The implanted medical device (IMD) collects physiological data via electrical, mechanical or chemical sensors. Some of this data may be used locally to modify therapy on a 'real-time' basis. The data is buffered in the IMD until such time that the device is interrogated by the external communications device (ECD). During this transaction, the ECD may also pass instructions received from the computing center to the IMD

The ECD contacts the computing center and passes the data on. The powerful computers at the computing center store and process the data, perhaps combining it with historical data of the same type from the same device, or perhaps with data from other implanted and medical devices. Comparisons of the data collected may be made with data from other patients with similar disease states, and therapy solutions constructed and compared.

The computing center then transfers instructions on modifications to therapy and data collection to the ECD. At the next opportunity for communications, the ECD transfers the instructions to the IMD and collects the next batch of data.

The invention is designed to operate asynchronously, as the possibility for breaks in the continuous and real-time communications of the three systems is likely. As the infrastructure for communications becomes more ubiquitous and robust, real-time control systems could be considered.

10. List all features of the device believed to be novel:

- ability to have high-power computing systems interact with implanted medical devices
- ability to use complex control algorithms in implanted medical devices
- ability to combine large amounts of historical data from a single or multiple medical devices for therapy prescription
- use of an external communications device and data network as a 'data bus' for an extended implanted medical device processing system

11. There has been no sale nor publication of this invention. No printed descriptions of this invention have been made to persons outside the company to our knowledge.

12. Inventor Signatures:

'99

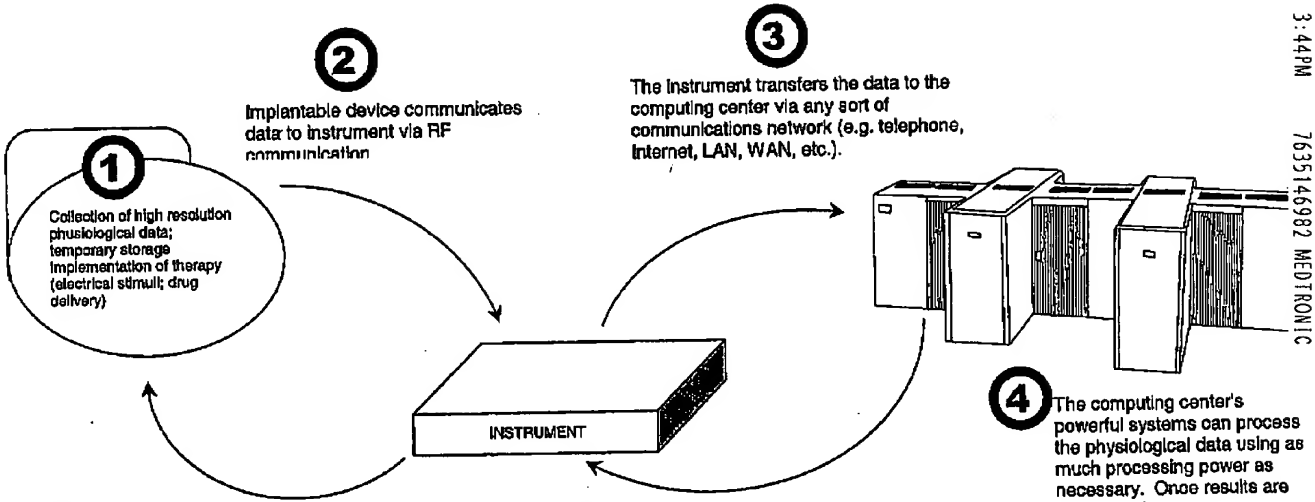
Nancy Perry Paul '99

Manager's Comments

13. How is this invention important to your products, plans or goals?

This invention adds to ...

14. Manager's Signature: Scott [illegible] T110, CRM



Initially the system would act in an asynchronous manner, where precise timing of data transfer and therapy changes is not critical. As the device-instrument and network communications become more ubiquitous and less reliant on specific hardware (e.g. RF head, network cables), the control loop could become more time-dependent.